REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 1-10, 12 and 13 are pending in this application.

Claims 1 and 13 have been amended to recite the transitional phrase "consisting essentially of" in order to exclude "an ion sensitive, hydrophilic polymer" from the aqueous liquid preparation of claim 1 and the aqueous eye drop of claim 13.

I. Telephonic Interview

Applicant appreciates the courtesies extended to Applicant's attorney by Examiner Frazier during the telephonic interview held August 30, 2011.

During the interview, Applicant's attorney proposed to exclude "an ion sensitive, hydrophilic polymer" from the claims by reciting "consisting essentially of" rather than "comprising". The Examiner stated that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s) of the claimed invention, and absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed to mean "comprising" for search purposes. The Examiner also stated that "an ion sensitive, hydrophilic polymer" could be considered to be an additional efficacious ingredient in the claimed composition.

In addition, the arguments presented in the paragraph bridging pages 6 and 7 of the Office Action, and the possibility of limiting the amount of the water-soluble metal chloride in the claims were discussed.

Applicant has carefully considered the Examiner's comments, and provides the following remarks in view of these comments.

II. Claim Rejection Under 35 U.S.C. § 103

The Examiner rejects claims 1-10, 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Kita et al. (US 6,307,052) in view of Lehmussaari et al. (US 5,795,913). As applied to the amended claims, Applicants respectfully traverse the rejection.

Claims 1 and 13 have been amended to recite the transition phrase "consisting essentially of". As discussed above, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s) of the claimed invention (see MPEP 2111.03).

The preparation and eye drops of claims 1, 10 and 13 require (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino] butyric acid ("bepotastine") or a pharmacologically acceptable acid addition salt thereof as the active ingredient, and a water-soluble metal chloride in a light-stabilizing effective amount of at least 0.2 w/v%.

The Examiner admits that while Kita et al. teach a medical composition comprising bepotastine, the reference does not specifically teach how the composition is formulated, and does not specifically teach a water-soluble metal chloride in a light-stabilizing effective amount of 0.2 w/v% or more (see Office Action, page 3, fourth paragraph). The Examiner asserts that Lehmussaari et al. remedy these deficiencies. Applicant respectfully disagrees.

The composition of Lehmussaari et al. requires the inclusion of an ion sensitive, hydrophilic polymer having viscosity, such as Carbopol, to control the formation of the polymer film on the cornea of the eye.

The reference discloses an ophthalmic composition in the form of a topical aqueous solution consisting essentially of an ophthalmologically active agent containing basic groups, an ion sensitive, hydrophilic polymer containing acidic groups in an amount of 0.004 to 1.5% by weight, at least one salt selected from the group of inorganic salts and buffers in a total amount of from 0.01 to 2.0% by weight, a wetting agent and a preservative, the ratio between salt and polymer being such that the solution exhibits a viscosity of less than 1000 mPas, and the pH of the solution is 4.0 to 8.0 (please see col. 2, line 57 to col. 3, line 6).

The reference teaches, "Thus one object of the invention is to provide an ophthalmic composition with a sufficiently high concentration of polymer to control the formation of the polymer film on the cornea of the eye, but which composition is still fluid enough for ocular topical application" (see col. 1, line 65 to col. 2, line 3).

Lehmussaari et al. use Carbopol as an ion sensitive, hydrophilic polymer in Examples 1 to 8. However, using an ion sensitive, hydrophilic polymer, such as Carbopol, in the aqueous liquid preparation of claim 1 and the eye drop of claim 13 would materially affect the basic and novel characteristics of the claimed compositions.

One skilled in the art would expect an ion sensitive, hydrophilic polymer (Carbopol) to cause nephelos as a result of the interaction between the polymer (Carbopol) and the sodium chloride, and that this interaction would influence the stability of the claimed preparation and eye drop. This interaction is clear from the teachings of WO 2009/142950 (please see page 4, lines 7-15 and pages 11-12, Table B, of the reference, copy enclosed).

In particular, when a carboxyvinyl polymer (Carbomer, i.e. Carbopol) was dissolved in water (Carbomer 1.0%), the nephelos was 12 NTU. On the other hand, when Carbomer (Carbopol) and sodium chloride were dissolved in water (1.0% Carbomer + 0.4% NaCl), the nephelos increased to 38 NTU. These results demonstrate that the Carbomer interacts with the salt to develop nephelos (see Table B of WO 2009/142950).

Therefore, one of ordinary skill in the art would recognize that an ion sensitive, hydrophilic polymer would materially affect the basic and novel characteristics of the aqueous liquid preparation of claim 1 and the eye drop of claim 13. As a result, an ion sensitive, hydrophilic polymer is excluded from the claimed compositions.

Accordingly, claims 1 and 13 would not have been obvious from the combination of Kita et al. and Lehmussaari et al.

In addition, Lehmussaari et al. teach that "for appearance and storage purposes, the use of a buffering salt is preferred to the use of e.g. sodium or potassium chloride as the viscosity reducing agent" (see col. 3, lines 55-58).

As mentioned above, the objective of Lehmussaari et al. is "to provide an ophthalmic composition with a sufficiently high concentration of polymer to control the formation of the polymer film on the cornea of the eye, but which composition is still fluid enough for ocular topical application" (see col. 1, line 65 to col. 2, line 3).

On the other hand, the objective of the claimed invention is to light-stabilize bepotastine or a salt thereof in an aqueous solution. A person of ordinary skill in the art would recognize that the light-stabilization of a drug and the viscosity control of a composition for local administration are completely different problems, and that there would be no reason to combine

Kita et al. with Lehmussaari et al. to obtain light-stabilization of bepotastine or a salt thereof.

Furthermore, Kita et al. disclose a benzenesulfonic acid salt or benzoic acid salt of bepotastine having low hygroscopicity and superior physico-chemical stability (see col. 1, lines 11-22). The reference does not teach or suggest the light-stabilization effects on bepotastine.

Lehmussaari et al. convert a composition having high viscosity due to the addition of an ion sensitive, hydrophilic polymer, such as Carbopol, to a composition having fluidity sufficient for ophthalmic treatment (see col. 1, line 65 to col. 2, line 3). The reference does not teach or suggest the light-stability of a drug.

A person having ordinary skill in the art would not have expected the absence of a color change and the absence of a precipitate upon irradiation of light in a solution containing bepotastine from the combination of the water-soluble metal chloride of Lehmussaari et al. and the bepotastine of Kita et al. The references have completely different objectives from the objective of the present application and each other, and provide no teaching or suggestion that the combination achieves light-stabilization.

Accordingly, one of ordinary skill in the art could not have combined Kita et al. and Lehmussaari et al. to arrive at the aqueous liquid preparation of claim 1 and the aqueous eye drops of claims 10 and 13 with a reasonable expectation of success.

Therefore, claims 1, 10 and 13 would not have been obvious over the references.

Claims 2-9 and 12 depend directly or indirectly from claim 1, and thus also would not have been obvious over the references.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Conclusion

For these reasons, Applicant takes the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that the rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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